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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
04/16/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	09/901,014	CHU, WEI-SING	
	Examiner	Art Unit	
	NELSON YANG	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *70,72-75,77-79,92-96 and 98-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70,72-75,77-79,92-96 and 98-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's addition of claims 105 and 106 are acknowledged and has been entered.

2. Claims 70, 72-75, 77-79, 92-96, 98-106 are currently pending and under examination

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 70, 72-75, 77, 78, 92-96, 105, 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al. [US 5,639,423] in view of Gravlee, Jr. [US 3,961,097] and Ishibashi et al. [US 5,984,881].

With respect to claim 70, Northrup et al. teach ultrasonic Lamb-wave devices (abstract) comprising a reactor equipped with a Lamb-wave transducer connected to an inductor (ultrasound transducer and generator) (column 7, lines 29-42) and a Lamb-wave sensor (first sensor) in a reaction chamber (column 7, lines 29-35), wherein the reaction chamber contains a Lamb-wave transducer that acts as an agitator, mixer, or sonochemical inducer (column 7, lines 28-35). Northrup et al. further teach temperature is monitored by measurement of the resistance of polycrystalline layers (column 9, lines 59-64), and also teach sensors for measuring density and viscosity (column 11, lines 40-48), as well as optical detection means (column 6, lines 36-52). Northrup et al. also teach a power source/control system (fig.1, column 6, lines 53-63) for

controlling the reaction, either by inductive coupling, capacitive coupling, or by electromagnetic coupling. Detection signals may be processed and stored by integrated microelectronic devices so that result interpretation and control mechanisms can be integrally contained (column 4, lines 40-45). Nothrup et al. further disclose that the system may be used to process tissues (column 5, lines 58-60). Northrup et al. do not teach a solution in the reaction chamber for fixing a tissue sample, nor do Northrup et al. specifically teach a central processing unit that adjusts the frequency or intensity of the ultrasound energy in response to a signal received from the sensor.

Gravlee, Jr., however, teaches that a method for fixing and processing a tissue specimen comprising sequentially immersing the specimen in a fixing agent, a dehydrating agent, a clearing agent, and paraffin while applying ultrasonic energy to the specimen during each of the steps, wherein the specimen and processing agents are contained in a vessel (column 2, lines 1-10). The intensity of application of the energy is controlled during the fixing steps to ensure that cavitation does not occur within the bath (column 2, lines 12-15). Gravlee, Jr. further teaches that the application of ultrasonic energy agitates the agent in the vessel, thus reducing the time required to process the specimen (column 3, lines 42-48).

Therefore, one of ordinary skill in the art at the time of the invention in possession of the ultrasonic device of Northrup et al., when presented with the method disclosed by Gravlee, Jr., would have been motivated to include solutions for fixing a tissue sample in the reaction chamber, in order to reduce the total preparation time needed when fixing and impregnating a tissue specimen in paraffin.

Ishibashi et al. further disclose an ultrasonic therapeutic apparatus comprising a computer (column 25, lines 49-68), which would contain a central processing unit, which controls the

power supply for driving the applicator for producing ultrasonic waves (column 25, lines 50-53), as well as an adjusting means feedback from an ultrasonic probe (column 4, lines 5-12 and column 40, lines 20-32). The adjusting means comprises a system controller which may measure and adjust the intensity of the ultrasound (column 16, lines 20-25) as well as include a safeguard (column 17, lines 30-37) to ensure that the ultrasound pulses are within an allowable range (column 19, lines 58-65)

Therefore, it would have been obvious to one of ordinary skill in the art to adapt the computer and adjusting means of Ishibashi et al. to the device of Northrup et al. for the purpose of performing the method of Gravlee, Jr., wherein the computer would be capable of adjusting the frequency and intensity of the ultrasound based on feedback from the ultrasound probe to ensure that the ultrasound is within an allowable range, in order to control the application of the ultrasound during the fixing steps to ensure that cavitation does not occur within the bath, as dictated by Gravlee, Jr., thus minimizing damage to the tissue without requiring manual intervention.

5. With respect to claims 72-74, Northrup et al. disclose that the density is measured (column 11, lines 45-47) by monitoring the wave characteristics (which would also allow for measurement of frequency of the ultrasound) using Lamb-wave sensors (column 11, lines 39-42), which are ultrasound sensors.

6. With respect to claim 75, Ishibashi et al. disclose that the computer is capable of processing received signals from the ultrasonic probe (column 25, lines 56-67).

7. With respect to claims 77 and 78, Northrup et al. disclose that the transducer is capable of producing Lamb waves with frequencies from 1 to 200 MHz (column 11, lines 3-10).

8. With respect to claim 92, Gravlee, Jr. teaches that the fixing agent may be 10% solution of formalin in water (column 3, lines 15-20).

9. With respect to claim 93, Gravlee, Jr. teaches that the dehydrating agent may be an alcohol (column 3, lines 23-25).

10. With respect to claim 94, Gravlee, Jr. teaches that the clearing agent may be xylene (column 3, lines 25-27).

11. With respect to claim 95, Gravlee, Jr. teaches that the tissue is impregnated with paraffin (column 3, lines 30-32).

12. With respect to claim 96, Northrup et al. teach pumps (LW_1, LW_2, LW_3) that pump solution into the reaction chamber and a pump that pumps solution out of the reaction chamber (LW_{DP}) and into the detection chamber (column 7, lines 35-37).

13. Claims 79 and 98-104 rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al. [US 5,639,423] in view of Gravlee, Jr. [US 3,961,097] and Ishibashi et al. [US 5,984,881], as applied to claim 70 above, and further in view of Vago [US 5,665,141].

With respect to claim 79, Northrup et al. do not specifically teach that the transducer produces ultrasound of a power in the range of 0.01-200 W/cm^2.

Vago, however, teaches a power density of 0.1 to 5 W/cm^2 (column 3, lines 45-55), and further discloses that the frequency and intensity of the ultrasound should be selected to avoid tissue damaging heating effects (column 7, lines 60-67). Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to ensure that the transducers of Northrup et al. are capable producing ultrasound of a power in the range of 0.1 to 5 W/cm^2 through normal optimization procedures known in the art, in order to avoid tissue-damaging heating effects.

14. With respect to claim 98, Northrup et al. teach the invention as disclosed above in claim 70. Northrup et al. do not specifically teach that the transducer produces ultrasound of a power in the range of 0.01-200 W/cm^2.

Vago, however, teaches a power density of 0.1 to 5 W/cm^2 (column 3, lines 45-55), and further discloses that the frequency and intensity of the ultrasound should be selected to avoid tissue-damaging heating effects (column 7, lines 60-67). Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to ensure that the transducers of Northrup et al. are capable producing ultrasound of a power in the range of 0.01-200 W/cm^2 through normal optimization procedures known in the art, in order to avoid tissue-damaging heating effects.

15. With respect to claim 99, Northrup et al. disclose that the transducer is further capable of producing Lamb waves with frequencies from 1 to 200 MHz (column 11, lines 3-10).

16. With respect to claims 100-102, the density is measured (column 11, lines 45-47) by monitoring the wave characteristics (which would also allow for measurement of frequency) using Lamb-wave sensors (column 11, lines 39-42), which are ultrasound sensors.

17. With respect to claim 103, Ishibashi et al. disclose that the computer is capable of processing received signal from the ultrasonic probe (column 25, lines 56-67).

18. With respect to claim 104, Northrup et al. teach pumps ((LW_1, LW_2, LW_3) that pump solution into the reaction chamber and a pump that pumps solution out of the reaction chamber (LW_{DP}) and into the detection chamber (column 7, lines 35-37).

19. With respect to claims 105, 106, Northrup et al. disclose that the transducer is capable of producing Lamb waves with a frequency of 1 MHz (column 11, lines 3-10).

Response to Arguments

20. Applicant's arguments with respect to claims 70, 72-75, 77-79, 92-96, and 98-104 have been considered but are moot in view of the new ground(s) of rejection. The following argument, however, has been addressed.

21. With respect to applicant's argument that Northrup et al. fails to teach that the transducer generates ultrasound of a frequency of at least 100 KHz (or 0.1 MHz), Northrup et al. discloses that the transducer is capable of producing Lamb waves with frequencies from 1 to 200 MHz (column 11, lines 3-10), which are all frequencies greater than 100 KHz. Since the limitation at least 100 KHz would encompass any frequency greater than or equal to 100 KHz, the limitation is anticipated, and applicant's argument is not found persuasive.

22. With respect to applicant's argument on p. 7, 8, that Northrup et al. fails to teach a central processor that controls an ultra sound generator to fix a tissue sample in a solution with no or minimal damage, it is noted that this appears to be an intended use of the central processor. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying

the claimed structural limitations. *Ex parte Masha*, 2 USPQ2d 1647 (1987). Since Gravlee et al. teach a central processing unit that allows for the control of the ultrasound, the structural limitations is anticipated. The fact that the transducers of Northrup et al. are capable of destroying tissue does not preclude the fact that the same transducers are also capable of fixing tissue samples, as this is a property of how the transducers are used and not due to the structural features of the transducers themselves, and therefore, since applicants are claiming an apparatus, and not methods of how the apparatus is used, applicant's arguments are not found persuasive.

23. For these reasons, the rejections have been maintained.

Conclusion

24. No claims are allowed.

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/
Patent Examiner, Art Unit 1641

/Long V Le/
Supervisory Patent Examiner, Art Unit 1641